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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,283	07/14/2000	Timothy T. Goodnow	109. 111. 114	6499

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	20

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/616,283	GOODNOW, TIMOTHY T.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

--The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *1-8,14-18,23 and 25-34*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 3. Applicant's reply has overcome the following rejection(s): The written description and new matter rejections over claims 23-25 under 35 U.S.C. 112, first paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claims 1, 3-6, 14, 16, 23-34 under 35 U.S.C. 103(a) as being unpatentable over Chan (EP 461, 462) in view of McLaughlin and Tadler et al., is maintained for reasons already of record.
In response to applicant's argument drawn to arguments previously presented and addressed in the previous office action, applicants are alleging that the references fail to show certain features of applicant's invention, however the feature upon which applicants are relying fail to be recited in the rejected claims. Limitations from the specification are not read into the claims. Therefore applicants' arguments are not persuassive because the claims are not limited.
Applicants argue about the use of the Chan reference. However the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments, contrary to applicants arguments.
Applicant argues that the Tadler et al., reference teach away from the claimed immunoassay and that Chan fails to disclose the claimed immunoassay.However applicants' argument is not persuassive since the rejection is based upon Chan (EP 461, 462) in view of McLaughlin and Tadler et al., and their teachings as a whole.
It is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments, contrary to applicants statements. "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, since Tadler et al., teach a binding agent which detects a gram-positive bacteria. Furthermore, it is noted that the claims do not require the binding agents to detect all of the gram-positive bacteria or even an entire class of microorganisms. Therefore, applicants' arguments are not persuassive.
In response to applicants' argument that there is no suggestion to combine the references, in this case, it would have been prima facie obvious to modify the simultaneous multiple analyte detection immunoassay taught by Chan by incorporating a set of binding agents as taught by McLaughlin and Tadler et al., since McLaughlin teach antibodies which specifically bind to gram-negative bacteria in order to determine their presence and/or absence while Tadler et al., teach well known binding agents that bind lipotechoic acid of gram-positive bacteria. One would have a reasonable expectation of success in utilizing a set of binding agents that bind gram-negative and positive bacteria in detection assays using known multiple analyte simultaneous detection assays to test samples of blood since using binding agents to detect antigens is well known in the art. Moreover both McLaughlin and Tadler et al, teach using samples just as recited in the claimed method of detection wherein the sample are whole blood, serum, and tissue and/or fluids. Therefore, the rejection is maintained as applicants' arguments are not persuassive.
Applicants argue that Tadler is not adequate to detect most bacteremias, however as previously stated, does not claim such, thus applicants arguments are not presuassive.
Again applicants argue that one would not have expected that an immunoassay as claimed would be effective.
However, the standard is that at least some degree of predictability is required and applicants have failed to presented evidence that there was no reasonable expectation of success. Obviousness does not require absolute predictability, rather at least some degree of predictability. Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made.Therefore, applicants' argument is not persuassive.
Likewise it is noted that none of the supplied references state that there was no reasonable expectation of success. Applicants object to the summary of applicants additional references, however the referecnes fail to teach that there was no reasonable expectation of success, rather the references assert that there may be associated disadvantages. Moreover, the articles reference the detection of a broad range of species however the instant claims only require that a bacterial antigen is detected, not each and every gram-negative and gram-positive bacterial antigen be detected. The standards for a successful test are not commensurate in scope to the standards that provide a reasonable expectation of success. The articles reference requirements not encompassed by the claims, like affordability and automation, however those standards are beyond the scope of the claims. Therefore, such arugments are not persuassive on the issue of reasonable expectation of success, since the standard of success measured by the instant claims is only whether a binding agent will be a gram-negative or gram-positive antigen in the screening assay.

Applicants argue that the use of the method has patentable weight, however, the functional limitation of the instant claims does not result in a structural difference. The prior art structure is capable of performing the intended use, thus it meets the claim. Therefore, for all of the reasons stated above, applicants' arguments are not persuasive and the rejection is maintained.

The rejection of claims 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over Chan, McLaughlin and Tadler et al., as applied to claims 1 and 14 above, and further in view of Chang et al., (US Patent 5,200,323) is maintained for the reasons already of record. Contrary to applicants argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce one would have a reasonable expectation of success in utilizing blood screened with in vitro screening assays to determine the safety of the blood prior to clinical use. Moreover Chan, McLaughlin and Tadler et al, all teach in vitro screening assays capable of determining the presence or absence of a bacterial antigen. Therefore, applicants' argument is not persuassive and the rejection is maintained.

The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Chan (EP 461,462) in view of Tadler et al., (1989) is maintained for the reasons previously stated in the prior office action. One would have a reasonable expectation of success in utilizing a set of binding agents that bind to gram-negative detection assays in a known multiple analyte simultaneous detection assay to test samples of blood. Moreover McLaughlin uses samples suitable for practice of the method of detection to include whole blood, serum, and tissue and/or fluids. Therefore, applicants' argument is not persuassive and the rejection is maintained.

The rejection of claims 8 and 18 under 35 U.S.C. 103(a) as being 2unpatentable over Chan (EP 461,462) in view of McLaughlin (US

Patent 4,683,196) is maintained for the reasons already of record. One would have a reasonable expectation of success in utilizing a set of binding agents that bind to gram-negative detection assays in a known multiple analyte simultaneous detection assay to test samples of blood. Moreover McLaughlin teaches radiometric techniques, like Chan.
Therefore, applicants' argument is not persuassive and the rejection is maintained.